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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,436	10/27/2003	Kathleen C.M. Campbell	SIU 7397	8942

321 7590 10/20/2005

SENNIGER POWERS
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/694,436	CAMPBELL, KATHLEEN C.M.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/10/05;7/28/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on February 10, 2005 and July 28, 2005 has being considered by the examiner.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,265,386 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent are to reduction of toxicity of ototoxiic drugs and radiation which comprises of administering a methionine or methionine type drugs to protect the individual thereof of toxicity. The only difference between the patent and the instant claims is with respect to mucositis which is a gastrointestinal disorder. In the instant application mucositis is a genus of the species

gastrointestinal disorder. Thus the claims of the instant application are an obvious variation of the patented claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Cambell US 6,265,386 B1.

Cambell discloses as to current claims 1 and 20 administering a compound methionine and structurally related compounds (abstract, and at col. 1 line 21-22), exposed to radiation.

- Claims 2 and 21 wherein the protective agent having the structural formula

wherein m is an integer from 0 to 3; n is an integer from 1 to 3; X = $-OR^1$, $-OCOR^1$, $-COOR^1$, -CHO, $-CH(OR^1)_2$, or $-CH_2OH$; Y = $-NR^2R^3$ or -OH; R^1 = H or a substituted or unsubstituted, straight or branched chain alkyl group having 1 to 6 carbon atoms; R^2 = H or a substituted or unsubstituted, straight or branched chain acyl group having 1 to 6 carbon atoms; and R^3 = H or a substituted or unsubstituted, straight or branched chain acyl group having 1 to 6 carbon atoms; or

a pharmaceutically acceptable salt thereof.

at col. 14 lines 30-44.

- Claims 3-6 and 22 wherein the protective agent is D-methionine, L-methionine, D, L methionine etc., at col. 15 line 25+
- claims 4- 9,16, 23-26 and 29-30 wherein the compound is administered prior (radiation/anti-tumor platinum-compound), simultanaeusly and subsequently at col. 19 lines 7-15.
- claims 10- 12 wherein the protective agent is administered 6 hours before at col.20 line9, 1 hour before to about 1 hour after as in claim 11 at col. 20 line 10, and one and half hour as in current claim 12 at col. 20 line 19.
- claims 13-15,17 and 26-28 administered orally, parenterally or topically at col. 20 line 25+, parenterally administration in the range of from about 1.0 to about 600 is disclosed in the reference as from about 1-to about 500 which is well within applicants

claim at col. 20 line 47+ in a blood serum level equivalent to that achieved by parenterally at col. 19 lines 45+.

Campbell discloses preventing or reducing mucositis with a compound-methionine L or D or D,L. Preventing or reducing mucositis does not alter the compound nor the composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim1 rejected under 35 U.S.C. 103(a) as being unpatentable over Cambell US 6,265,386 B1 in view of Gabrilove US 4,961,926.

Cambell teaches as to current claims 1 and 20 administering a compound methionine and structurally related compounds (abstract, and at col. 1 line 21-22), exposed to radiation.

- Claims 2 and 21 wherein the protective agent having the structural formula

$$CH_3(CH_2)_mS(CH_2)_n\text{-}CH(Y)\text{-}X$$

wherein m is an integer from 0 to 3; n is an integer from 1 to 3; X = $-OR^1$, $-OCOR^1$, $-COOR^1$, -CHO, $-CH(OR^1)_2$, or $-CH_2OH$; Y = $-NR^2R^3$ or -OH; R^1 = H or a substituted or unsubstituted, straight or branched chain alkyl group having 1 to 6 carbon atoms; R^2 = H or a substituted or unsubstituted, straight or branched chain acyl group having 1 to 6 carbon atoms; and R^3 = H or a substituted or unsubstituted, straight or branched chain acyl group having 1 to 6 carbon atoms; or

a pharmaceutically acceptable salt thereof.

at col. 14 lines 30-44.

- Claims 3-6 and 22 wherein the protective agent is D-methionine, L-methionine, D, L methionine etc., at col. 15 line 25+
- claims 4- 9,16, 23-26 and 29-30 wherein the compound is administered prior (radiation/anti-tumor platinum-compound), simultanaeusly and subsequently at col. 19 lines 7-15.
- claims 10- 12 wherein the protective agent is administered 6 hours before at col.20 line9, 1 hour before to about 1 hour after as in claim 11 at col. 20 line 10, and one and half hour as in current claim 12 at col. 20 line 19.
- claims 13-15,17 and 26-28 administered orally, parenterally or topically at col. 20 line 25+, parenterally administration in the range of from about 1.0 to about 600 is disclosed in the reference as from about 1-to about 500 which is well within applicants

claim at col. 20 line 47+ in a blood serum level equivalent to that achieved by parenterally at col. 19 lines 45+.

Although the above cited reference did not explicitely teach the supplement amount of the protective agent in the blood serum to be 10%, 20% or 70% as recited in current claims 18-19 and 31-32, the reference however teaches levels of the protective agent of the blood serum level as claimed but however teaches blood serum level equivalent to that achieved by parenterally at col. 19 lines 45+, nor did the reference teach mucositis (inflammation of the mucosal organ) but teaches gastrointestinal which is a mucosal organ.

Gabrilove teaches a method of preventing mucositis administering methionine at col.3 line 3 in the form of a granulocyte colony stimulating factor.

It would have been obvious for the one of ordinary skill in the art to combine the teachings of Campbell with that of Gabrilove, substitute the compound of Gabrilove with that of Campbell to treat mucositis, as it is known from the teaching of Gabrilove where an analog containing the same amino acid sequence having an additional methionine was used to treat mucositis.

One of ordinary skill in the art would have been motivated combine the teachings of the above cited prior art and expect a successful result in doing so as successful result has been shown in humans and animals that use methionine before or after exposure to radiation or platinum-containing chemotherapeutic agents. Methionine compounds have been used as protective agents to protect against gastrointestinal disorders.

Thus, the claimed invention was prima facia obvious to make and use at the time the invention was made.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVS
SVG
10/14/05

Christopher S. F. Low

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